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Over-the-counter β_2-agonist purchase versus script: A cross-sectional study

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Summary
Background: Purchase of short-acting β_2-agonist (SABA), but not anti-inflammatory asthma medication, is permitted in Australia without a doctor's prescription. This has been associated with worse asthma outcomes. We sought to compare the asthma outcomes between those purchasing SABA with and without a doctor's prescription.
Methods: Design: Cross-sectional study, using stratified randomisation of pharmacies. Setting: 43 pharmacies in Victoria, Australia.
Participants: Up to 10 consecutive adults purchasing β_2-agonists were recruited from each pharmacy, with 316 adults in total.

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Outcome measures: Participants underwent spirometry and questionnaires on respiratory health, asthma control, Quality of Life and medication adherence. Asthma severity was determined by GINA medication step. Regression analyses were performed that allowed for clustering by pharmacy.
Results: Of 316 individuals recruited (65% participation rate), 191 (60%) purchased a β_2-agonist with a prescription. Purchase of SABA without prescription was not associated with worse asthma outcomes or lung function. Mean ($\pm$SD) asthma control score (ACQ) was 1.65 $\pm$ 1.03; only 63 (20%) had well-controlled asthma (ACQ $<$ 0.75). Anti-inflammatory asthma medication was owned by 188 (60%) of participants, of whom 157 (83%) reported using this in the last 7 days. There was no correlation between medication adherence scores and asthma control. Forty-seven participants (15%) had an FEV_1 below 80% predicted and did not own an anti-inflammatory asthma medication.
Conclusion: Purchase of SABA without prescription was not associated with worse asthma outcomes in Australia. Although many patients reported symptoms of asthma, this did not appear to be associated with reported adherence to anti-inflammatory asthma medication.
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Background

Australia is unique amongst nations with universal health care systems in permitting the sale of short-acting β_2-agonists (SABA) for the treatment of asthma from pharmacies without a doctor's prescription ("over-the-counter"). In contrast, anti-inflammatory asthma medications such as inhaled corticosteroids (ICS), long-acting β_2-agonists (LABA) and their combinations can only be obtained by means of a doctor's prescription, with the purchase price heavily subsidised by the government.

Provision of SABA without prescription has been associated with sub-optimal asthma care and poor symptom control.[1–6] Individuals who purchased SABA without a doctor's prescription were more likely to have under-treated asthma and consult doctors less frequently.[2] High levels of asthma symptoms were described[3] and qualitative evidence suggested that purchase of SABA without a prescription was partly to avoid regular medical review.[5] Over-the-counter purchase of SABA medication has been controversial within Australia, with concerns that ready availability of SABA without oversight of a medical practitioner may result in SABA overuse and associated risks of sub-optimal asthma control.[7] In contrast, it might be expected that people with asthma would welcome the availability of SABA without a prescription, especially if there was no difference in cost.

The various studies examining SABA purchase without a prescription were performed prior to major asthma public health initiatives which have taken place over the past two decades and prior to the introduction of combination LABA and ICS inhalers. However, while asthma mortality rates in Australia and other countries with similar public health systems, such as the UK, have fallen, asthma mortality and morbidity remain a significant public health concern.[8]

Furthermore, recent studies suggest that asthma is commonly poorly controlled with high levels of symptoms.[9,10] Poor asthma control is usually attributed to inadequate use of asthma preventer medication.[9] Telephone survey data show that only 41% of Australians with daily asthma symptoms were taking inhaled corticosteroids, suggesting that a significant proportion of people with asthma are under-medicated with preventers.[10] In this context, the requirement of a prescription for SABA arguably provides an important opportunity for assessment of asthma control and the concurrent prescription of preventer medication.

In order to investigate the contribution of the availability of SABA without a doctor's prescription to adverse asthma outcomes, we studied people with asthma at the point of purchase of SABA from community pharmacies to determine whether there were any differences in asthma control, lung function, medication use and adherence amongst those who purchased SABA with or without a doctor's prescription.

Methods

The study was approved by the Alfred Hospital Human Research Ethics Committee and endorsed by The Pharmacy Guild of Australia.

Participants

Pharmacies

We set out to recruit a representative sample of community pharmacies. Pharmacies were randomly selected using a computer generated list of 956 metropolitan and rural pharmacies in Victoria.[11] We excluded (i) hospital associated pharmacies due to their non-representativeness and (ii) pharmacies in remote regions because of the significant travel costs that would have been incurred for low numbers of participants. Remoteness was based on the road distance people have to travel to reach a range of services classified according to the Pharmacy Access/Remoteness Index (PhARIA).[12] Sampling was stratified to ensure recruitment of metropolitan and regional pharmacies. Invitations were sent to 56 randomly selected pharmacies, of which 43 (77%) agreed to participate. The researcher spent up to one week in each pharmacy or until 10 patients were recruited, whichever occurred first. Data collection took place on site, between June 2004 and July 2005.

Participants

All individuals aged over of 16 years purchasing SABA medications for their personal use were eligible to

participate and were informed about the study by the pharmacist at the point of sale. Those who expressed interest were introduced to the researcher who obtained informed written consent. Participants completed:

1) Pre- and post-bronchodilator spirometry, performed according to ATS criteria[13] using a portable spirometer (Microlab, MicroMedical Ltd, Rochester UK) and interpreted using ECSC predicted normal values[14]
2) The European Community Respiratory Health Survey Questionnaire, modified to include current medication and smoking history[15]
3) An Asthma-related Quality of Life questionnaire (AQOL)[16]
4) The Asthma Control Questionnaire (ACQ)[17]
5) An assessment of adherence to asthma anti-inflammatory medications using a 4-item Adherence Questionnaire (ADH) previously validated in asthma[18,19] and the standard question "Have you used your asthma preventer in the past 7 days?"

There was complete ascertainment of eligible customers presenting to the pharmacy for purchase of asthma treatments. The researcher also recorded the number of eligible customers who did not participate. Their gender and estimated age-range was recorded to allow some demographic comparison of responders and non-responders.

Analysis

Sample size

The sample size was calculated to detect the minimum clinically important difference (MCID) of 0.5 in the ACQ between those receiving β_2-agonist with or without a doctor's prescription. Previous reports of the mean ($\pm$SD) Asthma Control Score were 1.49 $\pm$ 0.66 for the population with asthma. To detect the MCID with a power of 95% and a type 1 error rate of 0.05, assuming equal variances in the groups, we needed to recruit a minimum of 48 participants in each group. To allow for the effects of clustering by pharmacy, we assumed an intra-class correlation of 0.05 resulting in a design effect of 1.45 which inflated this to 70. Based on previous research[2] we assumed that only 30% of study participants would have a prescription for SABA which meant we would need to recruit 280 participants.

Statistical analysis

Data were entered in SPSS (Statistical Package for Social Sciences Version 17, Chicago, Ill: SPSS, 2008). Summary statistics for continuous variables are presented as mean $\pm$ SD unless otherwise stated. Differences between means were assessed with Student's *t*-test or Mann-Whitney *U* Test for skewed data. We used Chi-square to test differences in proportions between categorical variables and Spearman's correlation to study the relationship between ACQ and adherence scores. Linear regression models with robust variance estimation accounting for the effects of clustering by pharmacy were fitted to determine the relationships between prescription use, asthma severity, ACQ, AQOL, ADH and FEV_1. As ACQ values were not normally distributed, a square-root transformation was applied prior to this analysis. Similarly, AQOL scores were log-transformed. *P*-values of less than 0.05 were considered significant.

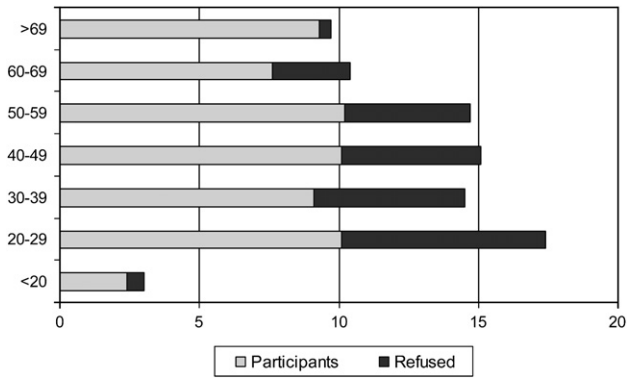

Figure 1 Percentage of participants compared to non participants by age. Older people were significantly less likely to refuse to participate in the study compared to younger age groups ($p < 0.001$).

Asthma severity

In accordance with recent guidelines, we estimated asthma severity by determining treatment according to the GINA treatment step (GINA 1-5).[20,21] Individuals purchasing their first asthma medication (who had no medication use prior to their index pharmacy presentation) were categorised as "No Prior Medication".

Results

Participants

Of 479 eligible individuals, 316 (66%) participated in the study. Younger people were less likely to participate (see Fig. 1).

The demographics of participants are listed in Table 1. A previous doctor-diagnosis of asthma was reported by 295.

There were 126 (40%) life-long non-smokers, 83 (26%) current smokers and 107 former smokers. Of the former and current smokers, 25% (80) had less than a 10 pack-year smoking history while 35% (110) had a greater than 10 pack-year history.

Purchase of SABA without a prescription

SABA medication was purchased without a prescription by 125 (39.6%), while 191 (60.4%) had a doctor's prescription. Simple between-group comparisons of lung function, ACQ, AQOL and ADH scores are presented in Table 2, revealing that purchase with a prescription appeared to be associated with worse asthma control, asthma related quality of life and lung function.

Further analysis was conducted to ascertain the major associations with ACQ and to correct for asthma severity, Health Care Card ownership and the effects of clustering by pharmacy (Table 3). This analysis revealed no significant differences in asthma control between those who purchased SABA with or without prescription. The major factor determining the ACQ score was asthma severity as determined by GINA medication step. Health Care Card ownership was also associated with a small but significant increase in the ACQ score, indicating worse asthma control.

Table 1 Participant demographics. There were 316 study participants. Adherence scores were only determined in those taking regular inhaled preventer medication (n=188). Four participants did not provide sufficient information for inclusion in the calculation of medication step. Sixteen participants claimed that their anti-inflammatory medication was "as needed" and were therefore classified as Step 1.

Age (years) Mean ± SD	46.7 ± 19 yrs
Female	173 (55%)
Mean (±SD) FEV_1 maximum post-bronchodilator (L)	2.41 ± 0.97
Mean (±SD) Asthma Control Score (<0.75 well controlled, >1.5 uncontrolled)	1.65 ± 1.03
Mean (±SD) Asthma-related Quality of Life	0.86 ± 0.74
Mean (±SD) Adherence Score	2.04 ± 1.6
Health Care Card Owners	160 (50.6%)
Classification of Severity[a]	
No prior diagnosis	11 (3.5%)
GINA step 1	129 (41.3%)
GINA step 2	24 (7.7%)
GINA step 3	45 (14.4%)
GINA step 4	88 (28.2%)
GINA step 5	15 (4.8%)
Missing data	4

[a] Asthma severity was classified by the GINA treatment step.[21]

Similarly, the major determinant of QOL was asthma severity categorised by GINA treatment step, rather than purchase of medication with a prescription (data not shown).

Reliever use

Only 76 participants (24%) used no SABA medication on most days, 102 (32%) used 1 to 2 puffs most days, and 59 (19%) used 3 to 4 puffs most days. The remaining 78 participants (25%) used 5 or more puffs on most days.

Anti-inflammatory asthma medication use, asthma control and quality of life

Ownership of asthma preventer (anti-inflammatory) medication was high with 60% (188) having an asthma preventer. Of these, 114 (61%) used a salmeterol/fluticasone combination, while an eformoterol/budesonide combination was used by 18 (10%). The remainder used inhaled corticosteroids without a LABA, or nedocromil. After converting the prescribed corticosteroid dose to beclomethasone equivalents, the median dose of inhaled corticosteroids per day was 500 (IQR 400-1000 mcg) for the group as a whole.

In accordance with convention, we considered an ACQ score of <0.75 as well controlled, between 0.75 and 1.5 as partly controlled and >1.5 as uncontrolled. Asthma was rated as well controlled in 63 (20%), partly controlled in 85 (27%) and uncontrolled in 131 (42%), with 3 missing data. In the group with uncontrolled asthma, 47 (36%) did not have anti-inflammatory asthma medication. A further 34 participants had fixed irreversible airflow obstruction on spirometry (FEV_1< 70% predicted) and a greater than 10 pack-year smoking history. We classified this group as having a more correct diagnosis of COPD and their ACQ was correspondingly poor (2.4 ± 0.83) and were not included in this comparison.

Adherence to asthma medications

All participants were asked if they had taken their anti-inflammatory asthma medication in the past 7 days. Of the 188 (61%) of individuals who had such medication, 157 (83%) claimed to have used it in the past 7 days. Simple comparison showed that individuals who purchased their SABA with a prescription were more likely to have used preventer medication in the past 7 days (Chi-squared 5.06, $p = 0.02$). We further assessed adherence to asthma anti-inflammatory medication in those participants who owned an asthma preventer medication using a 4-item questionnaire (ADH)[18,19] where a lower score indicated better medication adherence (Table 1). We found no significant correlation between the asthma control score and ADH for controller/preventer

Table 2 Lung function, Asthma-related Quality of Life and Asthma Symptom Control for study participants according to purchase of SABA with and without a prescription. Comparisons were made by t-test if the data were normally distributed or Mann-Whitney test (MW) if the data were skewed.

Mode of reliever purchase	Prescription (n = 191)	Without prescription (n = 125)	p-value	Missing data (n)
Age (years) Mean ± SD	53.6 ± 19.4	38.7 ± 13.6	<0.001	0
FEV_1% predicted Mean ± SD	78.7 ± 24.8	83.6 ± 21.1	0.07	3
FEV_1 pre-bronchodilator Mean ± SD	2.16 ± 0.95	2.79 ± 0.86	<0.001	3
Change in FEV_1 (%)	4.42 ± 9.2	6.74 ± 9.5	0.034	7
% on controller medications	65% (n = 126)	50% (n = 62)	0.003	6
AQOL median (25%, 75%)	0.71 (0.32, 1.42)	0.54 (0.33, 0.92)	0.018	2
Asthma Control Score median (25%, 75%)	1.57 (0.86, 2.57)	1.43 (0.86, 1.93)	0.027	3
Adherence Score (4 item) median (25%, 75%)	2.00 (0.00, 3.00)	3.00 (2.00, 4.00)	<0.001	137

Abbreviations: SD = Standard Deviation.

Table 3 Asthma control by purchase with and without script, by gender, Health Care Card ownership and GINA medication step level. Parameters and estimated marginal means for the Asthma Control Questionnaire using a linear regression analysis to account for the effects of clustering by pharmacy. This shows that asthma severity by GINA step was the major determinant of Asthma Control score rather than purchase with or without a prescription. Health Care Card holders also had a poorer Asthma Control score likely indicative of lower socioeconomic status and age.

		Marginal Means			Parameter Estimates			
		Mean Asthma Control Score	95% CI Lower	95% CI Upper	Regression coefficient	95% Confidence Interval		*p*-value
						Lower	Upper	
All participants		1.67	1.52	1.83				
Purchase of β2-agonist with prescription		1.69	1.47	1.92	0.01	−0.110	0.131	0.9
Purchase of β2-agonist without prescription		1.66	1.45	1.89				
Gender: Female		1.61	1.41	1.82	−0.053	−0.132	0.026	0.2
Gender: Male		1.74	1.58	1.91				
Health Care Card holder		1.84	1.62	2.07	0.0560	0.016	0.236	0.02
Non-Health Care Card holder		1.52	1.33	1.72				
Asthma Severity Medication Step	No Prior Medication	1.58	1.06	2.21	−0.474	−0.755	−0.194	0.001
	GINA step 1	1.20	1.03	1.38	−0.638	−0.827	−0.449	0.001
	GINA step 2	1.41	1.09	1.77	−0.544	−0.790	−0.298	<0.001
	GINA step 3	1.40	1.15	1.67	−0.549	−0.775	−0.324	<0.001
	GINA step 4	1.73	1.52	1.95	−0.417	−0.608	−0.227	<0.001
	GINA step 5	3.00	2.40	3.66				

medication use (Spearman's rho = 0.048, $p = 0.6$). We further examined this relationship using linear regression and showed that purchase of SABA with a prescription, gender, ownership of a Health Care Card and asthma severity were not associated with adherence scores. However increasing age was associated with improved adherence scores (Table 4).

Abnormal lung function

Almost half of the participants (141 or 45%) had impaired lung function with an FEV_1 less than 80% predicted. Fifty (34.7%) of these purchased their SABA without a doctor's prescription. Linear regression analysis allowing for the effects of clustering by pharmacy of post-bronchodilator FEV_1 confirmed that purchase of SABA without

Table 4 Adherence by purchase with and without script, gender, Health Care Card ownership and GINA medication step level. Parameters and estimated marginal means for Adherence Score (ADH) in the 188 participants who owned a preventer medication using linear regression analysis to account for the effects of clustering by pharmacy. Age was a predictor of improved 30 Adherence score. There was no association between asthma severity and adherence score.

		Marginal Means			Parameter Estimates			
		Mean Adherence Score	95% CI Lower	95% CI Upper	Regression coefficient	95% Confidence Interval		*p*-value
						Lower	Upper	
All participants		0.29	0.17	0.41				
Age					0.969	0.950	0.989	0.003
Purchase of β2-agonist with prescription		0.25	0.12	0.37	0.65	0.284	1.478	0.3
Purchase of β2-agonist without prescription		0.34	0.17	0.50				
Gender: Female		0.29	0.12	0.46	0.985	0.401	2.422	0.9
Gender: Male		0.29	0.17	0.41				
Health Care Card holder		0.25	0.14	0.37	0.694	0.360	1.339	0.3
Non-Health Care Card holder		0.33	0.17	0.48				
Asthma Severity Medication Step	GINA step 1	0.28	0.00	0.57	3.104	0.424	22.721	0.3
	GINA step 2	0.28	0.07	0.49	3.055	0.262	35.672	0.4
	GINA step 3	0.45	0.32	0.59	6.531	0.805	52.964	0.08
	GINA step 4	0.40	0.27	0.54	5.337	0.637	44.693	0.1
	GINA step 5	0.11	−0.09	0.32	1.0			

a prescription was not associated with worse lung function ($B = 0.014$; 95% CI -0.133—0.160). Again, asthma severity was strongly associated with reduced lung function ($p < 0.001$). Of those with impaired lung function 47 (15%) did not own preventer medication.

Discussion

In this sample of 316 people with asthma recruited from randomly selected community pharmacies in Victoria, purchase of SABA medication without a doctor's prescription was not associated with worse asthma outcomes. This contrasts with a number of previous reports[1—6] and suggests that the current environment of asthma care within Australia ensures good access to anti-inflammatory asthma medication despite the ready availability of SABA without a medical prescription. The similarity of asthma treatment guidelines in nations with comparable health care systems, such as Canada and the UK,[22,23] adds further support to the generalisability of our findings which have substantial implications for the provision of accessible asthma care.

Several reasons may account for this finding. In this study, asthma preventer ownership was high compared to previous reports, with 60% of individuals stating they owned an asthma preventer inhaler, of whom 83% claimed to have used it in the past 7 days. In a selected sample of middle-aged patients from Tasmania, Kandane-Rathnayake and colleagues reported that 78% of participants with asthma used SABA of which 43% also reported using an asthma preventer, indicating that 55% of this group owned asthma preventer medication.[24] This is comparable to our findings where the method of recruitment ensured that all participants owned a SABA, of whom 60% also owned a preventer. However, these findings differ greatly from a telephone survey of people over the age of 5 years recruited from the community which showed that only 28% of those reporting SABA medication use in the past two weeks also used inhaled corticosteroids.[10] Our recruitment of people with asthma buying SABA from community pharmacies is likely to have recruited people with more symptomatic and/or more severe asthma, who may be more likely to engage in regular health review.

In our study, 15% of participants whose lung function was below 80% predicted, did not use anti-inflammatory asthma medication, suggesting that additional prescription of anti-inflammatory asthma medication is probably indicated. This figure is much less than the report by Kandane-Rathnayake and colleagues which showed that while 55% of patients using SABA owned an asthma preventer, only 26% of this middle-aged cohort appeared to be taking it adequately as judged by a symptom-based severity score.[24] Comparable statistics suggesting low use of asthma preventer medications have been found in surveys based on asthma symptoms in Australia and in Europe.[9,10]

In Australia low income groups such as pensioners qualify for a Health Care Card which provides a greater subsidy for prescribed medication. This provides a financial incentive to purchase medication with a doctor's prescription for those of lower income, a group known to be at greater risk of poor asthma outcomes.[25] Despite this, those with a Health Care Card had significantly worse asthma control than those without a card, suggesting that this policy does not completely protect lower-income groups with asthma from the adverse health effects of their socio-economic status.

There are several limitations of this study. The study was designed with asthma control scores as the primary outcome. The lack of any association between purchasing SABA without a prescription and asthma control is unlikely to be due to lack of statistical power as the minimum important clinical difference of 0.5 lies well outside the 95% confidence interval for the relevant coefficient in the regression model (Table 3). However it is possible that type II statistical errors have occurred for some secondary outcome variables. Further research, including the use of qualitative methods could expand on our findings.

Our method of recruitment of people with asthma at the 'point of sale' of SABA was an efficient method that reliably allowed us to address differences in self reported asthma control and lung function according to whether SABAs were bought with or without a prescription. In recruiting the intended sample with current asthma, we were also more likely to have recruited those with poorer asthma control and/or more severe asthma. Regulations that limit the purchase of SABA asthma medications without a doctor's prescription to those with a previous diagnosis of asthma would also exclude those with milder or unrecognised disease. While we recruited participants from randomly selected pharmacies, the findings should not be generalised to remote rural settings. They also do not account for seasonal variability. Our findings must also be interpreted with some caution in those countries with different access to health care and different funding of health care services. Critically, our findings should not be interpreted that people should not attend doctors for asthma care. Our study revealed that 15% (47) of participants in our study had lung function below 80% predicted and yet did not own an asthma preventer, suggesting that this group in particular would benefit from medical care. Our findings should be used to support recommendations from pharmacists to patients purchasing over-the-counter SABA that they attend a physician for preventer care. This should especially be the case if purchase of SABA is frequent.

Conclusions

In summary, this study indicates that the Australian policy of the provision of SABA without a doctor's prescription is not associated with worse asthma control in those attending pharmacies for purchase of asthma medications. This is consistent with the opinion that ready access to SABA medication may even be beneficial to those with asthma because of improved convenience and accessibility. However as many as 15% of people attending pharmacies for SABA may benefit from additional asthma preventer medication, which reinforces the role of pharmacies as a site for delivering interventions to improve health outcomes in people with asthma.

Funding

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Conflicts of interest

JD has received support for conference travel and speaker's honoraria from Glaxo-Smith-Kline, AstraZeneca and Schering Plough. She has undertaken industry funded research for GSK & AstraZeneca. She is on advisory boards for AstraZeneca and GSK. She has received support for investigator- initiated studies from Novartis. MA was a consultant to GSK on the Australian Asthma Management Study. He has received a speaker's honorarium from Boehringer-Ingelheim and conference travel support from AstraZeneca. He was a member of the Scientific Committee for the Landmark Symposium, which was sponsored by GSK, but did not receive any honorarium. SMS has received speaker's honoraria from Astra Zeneca. KS, EM, RA & DG have no competing interests to declare.

Authors contributions

JD and DG initiated the study and MA, KS, RA, SMS and EM contributed to the study design. KS participated in the selection of the pharmacies and MA assisted with randomisation. DG and EM collected the information in the pharmacies. JD, DG, MA and Rory Wolfe analysed the data. JD and DG prepared the manuscript, and all authors contributed to the final version. All authors have read and approved the final manuscript. JD will act as guarantor for the paper. All authors read and approved the final manuscript.

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